FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee (PDAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)

FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
October 16, 2014

AGENDA

The committees will discuss safety data from observational studies and a meta-analysis of randomized controlled clinical trials that have been conducted since the original signal of serious neuropsychiatric adverse events with CHANTIX (varenicline tartrate tablets, NDA 21928, Pfizer, Inc.) emerged. The committees will also discuss whether any action needs to be taken with regard to how this risk is described in product labeling.

8:00 a.m.	Call to Order and Introduction of Committee	**Ruth Parker, MD** Acting Chairperson, PDAC
8:05 a.m.	Conflict of Interest Statement	**Kalyani Bhatt, BS, MS** Designated Federal Officer, PDAC
8:10 a.m.	FDA Introductory Remarks/ Regulatory History	**Judith A. Racoosin, MD, MPH** Deputy Director for Safety Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE II) Office of New Drugs (OND), CDER, FDA
8:25 a.m.	**FDA PRESENTATION**	
	Regulatory Requirements and Guidance Recommendations for Warnings and Precautions and Boxed Warning Sections	**Eric Brodsky, MD** Labeling Team Leader Study Endpoints and Labeling Development Office of New Drugs (OND), CDER, FDA
8:35 a.m.	**INDUSTRY PRESENTATIONS**	
	Background and Overview	**Christopher Wohlberg, MD, PhD** Vice President and Safety Surveillance & Risk Management Group Head, Global Innovative Pharma Pfizer, Inc.
	Current Clinical Trials Data Regarding Neuropsychiatric Events	**Lawrence Samuels, PhD** Senior Director, Medical Affairs Pfizer, Inc.

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AGENDA (cont.)

INDUSTRY PRESENTATIONS (cont.)

	Observational Studies Data Regarding Neuropsychiatric Events & Public Health Perspectives	**Robert West, PhD** Professor of Health Psychology Health Behaviour Research Centre Cancer Research UK Health Behaviour Research Centre Department of Epidemiology and Public Health University College London
9:50 a.m.	Clarifying Questions to Industry	
10:10 a.m.	**BREAK**	
10:25 a.m.	**FDA PRESENTATIONS**	
	Clinical Perspective on Neuropsychiatric Adverse Events	**Celia Winchell, MD** Medical Team Leader, Addiction Products Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE II) Office of New Drugs (OND), CDER, FDA
	Statistical Review of Meta-analysis	**Eugenio Andraca-Carrera, PhD** Reviewer, Division of Biometrics VII Office of Translational Sciences (OTS) CDER, FDA
	Review of Observational Studies	**Natasha Chen, PhD** Reviewer, Division of Epidemiology Office of Surveillance and Epidemiology (OSE) CDER, FDA
11:40 a.m.	Clarifying Questions to FDA	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Charge to the Committee	**Judith A. Racoosin, MD, MPH**

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AGENDA (cont.)

2:10 p.m. Questions to the Committee/Committee Discussion

3:00 p.m. **BREAK**

3:10 p.m. Questions to the Committee/Committee Discussion (cont.)

5:00 p.m. **ADJOURNMENT**